

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference PCT-12361	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/08549	International filing date (day/month/year) 01.08.2003	Priority date (day/month/year) 06.08.2002
International Patent Classification (IPC) or both national classification and IPC C12N15/82		
Applicant ICON GENETICS AG et al.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

- This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 02.03.2004	Date of completion of this report 31.08.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Guarinos Viñals, E Telephone No. +49 89 2399-7228



INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

International application No. PCT/EP 03/08549

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-38 as originally filed

Claims, Numbers

1-24 as originally filed

Drawings, Sheets

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-20, 22
	No: Claims	21, 23, 24
Inventive step (IS)	Yes: Claims	1-20
	No: Claims	22
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

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Section V

D1: DRESCHER ANJA ET AL: 'The two largest chloroplast genome-encoded open reading frames of higher plants are essential genes' PLANT JOURNAL, BLACKWELL SCIENTIFIC PUBLICATIONS, OXFORD, GB, vol. 22, no. 2, April 2000 (2000-04), pages 97-104.

D2: WO 02 057466 A (MUEHLBAUER STEFAN ;HERZ STEFAN (DE); EIBL CHRISTIAN (DE); HUANG FO) 25 July 2002 (2002-07-25).

D3: WO 99 29837 A (EUROP LAB MOLEKULARBIOLOG ;ZHANG YOUMING (DE); BUCHHOLZ FRANK (DE)) 17 June 1999 (1999-06-17).

Novelty (Art 33(2) PCT)

Document D1 discloses DNA molecules containing (i.e. comprising) one region homologous to a region of a plastome. Vectors p Δ ycf1 and pycf1 in Figure 1 contain (i.e. comprise) the sequences *rrn4.5*, *rrn5*, *trnR* and *rps15* and vectors p Δ ycf2 and pycf2 in Figure 2 contain the sequences *rpl12*, *rpl23*, *trnI*, *ycf15* that are homologous to the corresponding sequences in the plastome.

Also disclosed in D1 are tobacco plants transformed with said vectors.

Therefore the subject-matter of claims 21 and 23 is not novel according to Art 33(2) PCT.

Although the plants disclosed in D1 have been obtained by another recombination method, a product is not rendered novel merely by the fact that it is produced by means of a new process. The plant of claim 24 is obtainable by the method disclosed in the present application and also by the method disclosed in D1.

Therefore the subject-matter of claim 24 is not novel according to Art 33(2) PCT.

Inventive step (Art 33(3) PCT)

Document D1 discloses several DNA molecules containing (i.e. comprising) one region homologous to a region of a plastome and different sequences of interest (*aadA*, *aadA* and *ycf1* or *aadA* and *ycf2*).

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It would be obvious for a person skilled in the art to provide a library of DNA molecules containing one region homologous to a region of a plastome and different sequences of interest in the light of the teaching of D1 and the general knowledge on libraries. Therefore the subject-matter of claim 22 is not inventive according to Art 33(3) PCT.

Document D2 discloses a method for plastid transformation in higher plants which comprises introducing into plant plastids a first and a second DNA molecule.

The first DNA molecule contains a first region homologous to a region of the plastome and a first sequence of interest, where the first region homologous to a region of the plastome is the left flank of the genes *rpoA*, *petA* or *ycf3* and the first sequence of interest is the *aadA* gene (see Fig. 3, Fig. 8 and Fig. 13).

The second DNA molecule contains a second region homologous to a region of the plastome and a second sequence of interest, where the second region homologous to a region of the plastome is the right flank of the genes *rpoA*, *petA* or *ycf3* and the second sequence of interest is the *rpoA-GUS*, *petA-uidA* or *ycf3-GFP* gene (see Fig. 4, Fig. 10 and Fig. 15).

The differences between D2 and the subject matter of claim 1 is that in the method of claim 1 the first and the second sequence of interest are homologous and consequently, after integration of the two molecules, the integration sequence contains at least a portion of said first and at least a portion of said second sequence of interest as a continuous sequence.

Therefore, in the light of D2, the problem solved by the present application is the provision of an alternative method for plastid transformation in higher plants, the solution being the method of claim 1.

Document D3 discloses a method comprising a first DNA molecule and a second DNA molecule that comprises at least two regions of sequence homology to regions on the first DNA molecule. However in D3 recombination takes place between said first and second DNA molecule and, actually, the method of D3 corresponds to a cloning method, not to a transformation method.

Therefore, in the light of the prior art, the solution provided by the present application is not obvious and, consequently, claims 1-20 are inventive according to Art 33(3) PCT.